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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,114	04/19/2004	Jeffrey I. Frank	ARCD:394US	1458

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EXAMINER

WILLIAMS, KENNETH C

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,114

Applicant(s)

FRANK ET AL.

Examiner

Kenneth C. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-17 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-21 and 26-29 is/are rejected.
- 7) ☒ Claim(s) 22-25 and 30-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/11/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on January 11, 2006, amended claims 1, 5, 11, 12, 15, 17, 21, 23, 26 and 29-32; cancelled claims 4 and 18; formal drawings; and amendments to the specification are acknowledged.

2. Claims 1-3, 6-8, 10 and 11 *stand* rejected under 35 U.S.C. 102(b) as being anticipated by Milder (U.S. Patent No. 5281215). Claims 5 and 12-14 *stands* rejected under 35 U.S.C. 103(a) as being unpatentable over Milder in view of Dobak III et al. (U.S. Patent No. 6312452). Claim 9 *stands* rejected under 35 U.S.C. 103(a) as being unpatentable over Milder in view of Bilweis (U.S. Patent No. 6179831). Claims 15 and 16 are *newly* rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak III et al. in view of Milder. Claims 17, 19 and 20 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over Milder in view of Hammack et al. (U.S. Patent No. 6679906). Claim 21 is *newly* rejected under 35 U.S.C. 103(a) as being unpatentable over Milder in view of Sieben et al. (U.S. Patent No. 5833688). Claims 26-28 are *newly* rejected under 35 U.S.C. 103(a) as being unpatentable over Milder in view of Dobak III et al., further in view of Sieben et al. The following new and reiterated grounds of rejection are set forth:

Claim Objections

3. Claim 6 is objected to because of the following informality: claim 6 is dependent upon a cancelled claim. In order to examine the claim, the Examiner will consider claim 6 as dependent upon claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 29 lacks a physical transformation or the production of a useful, concrete and tangible result from the calculation of the thermal transport property. It is the Examiner's position that the calculation, as stated in claim 29, is producing an abstraction, which does not overcome a 35 U.S.C. 101 rejection. Claims 30-32 meet this burden for a computer readable media by producing useful, concrete and tangible results.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Milder (U.S. Patent No. 5281215).

In regards to Claims 1-3, 6-8, 10 and 11, Milder discloses a heat transfer probe comprising "an inner tube having an opening" (See Figure 1, element 14, also see column 3, line 33), "an outer tube surrounding the inner tube" (See Figure 1, element 16, also see column 3, line 31), "a tip adjacent the opening" (See Figure 1, element 12, also see column 3, line 28), "a first temperature sensor coupled to the tip" (See Figure 14, element 122, also see column 7, lines 32-38), "a second temperature sensor spaced apart from the first temperature sensor", (See Figure 14, element 122, also see column

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7, lines 36-40), "the inner and outer tubes defining concentric channels" (See column 8, lines 32-33), "a third temperature sensor coupled to an outlet of the outer tube" (See Figure 14, element 122), "the inner tube comprising a first material" (See Figure 1, element 14), "the outer tube comprising a second material" (See Figure 1, element 16), "the tip comprising a third material having a thermal conductivity different from that of the first or second material" (See Figure 1, element 22, column 3, lines 39-45), "the first and second material being the same" (See column 5, lines 39-49) and "the temperature sensor comprising a thermocouple" (See Figure 14, element 122, also see column 7, lines 29-31).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 5 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215) in view of Dobak III et al. (U.S. Patent No. 6312452).

In regards to Claim 5, Milder discloses a heat transfer probe (See Claim 1 Rejection). Milder does not disclose “an isolation member coupling the second temperature sensor to the outer tube”. Attention is directed to the Dobak III et al. reference, which in an analogous field of endeavor discloses a heat transfer probe with a thermocouple mounted on the end of a guidewire, which is coupled to the outer tube of the probe (See Dobak III et al. Figure 23, element 440). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the isolation member of Dobak III et al. to the device of Milder to utilize an isolation member to couple a temperature sensor to the outer tube in order to monitor the temperature of a tissue at a distance away from the probe.

In regards to Claims 12-14, Milder discloses a heat transfer probe comprising “an inner tube having an opening and comprising a first material” (See Figure 1, element 14, also see column 3, line 33), “an outer tube surrounding the inner tube and comprising a second material” (See Figure 1, element 16, also see column 3, line 31), “the tip adjacent the opening and comprising a third material having a thermal conductivity different from that of the first or second material” (See Figure 1, element 22, column 3, lines 39-45), “a first temperature sensor coupled to the tip” (See Figure 14, element 122, also see column 7, lines 32-38) and “a second temperature sensor spaced

apart from the first temperature sensor", (See Figure 14, element 122, also see column 7, lines 36-40).

Milder does not disclose "an isolation member coupling the second temperature sensor to the outer tube". Attention is directed to the Dobak III et al. reference, which in an analogous field of endeavor discloses a heat transfer probe with a thermocouple mounted on the end of a guidewire, which is coupled to the outer tube of the probe (See Dobak III et al. Figure 23, element 440). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the isolation member of Dobak III et al. to the device of Milder to utilize an isolation member to couple a temperature sensor to the outer tube in order to monitor the temperature of a tissue at a distance away from the probe.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215), further in view of Bliweis (U.S. Patent No. 6179831).

In regards to Claim 9, Milder discloses a heat transfer probe (See Claim 1 Rejection). Milder does not disclose "a probe holder coupled to the outer tube". Attention is directed to the Bliweis reference, which in a similar field of endeavor discloses a heat transfer probe with a probe holder coupled to the outer tube of the probe (Figure 5, element 32; column 6, lines 62-64). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the probe holder of Bliweis to the device of Milder to safely operate the probe.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak III et al. (U.S. Patent No. 6312452) in view of Milder (U.S. Patent No. 5281215).

In regards to Claims 15 and 16, Dobak III et al. discloses a system comprising "a heat transfer probe" (See Figure 3), "an inner tube having an opening" (See Figure 3, element 42), "an outer tube surrounding the inner tube" (See Figure 3, element 46, see also column 11, lines 10-13), "a tip adjacent the opening that terminates the inner and outer tubes", (See Dobak III et al. Figure 23), "a source for delivering working fluid" (See Figure 25, element 452, see also column 22, lines 62-64), "a pump coupled to the source", (See column 15, lines 6-10), "a controller to control the flow of working fluid to effect heating or cooling of tissue adjacent the probe" (See Figure 25, element 458, see also column 22, lines 59-62) and "the controller receiving feedback from the temperature sensor to adaptively control the flow of working fluid based on a sensed temperature" (See column 22, lines 59-62).

Dobak III, et al. does not disclose "a plurality of temperature sensors coupled to the tip". Attention is directed to the Milder reference, which in an analogous field of endeavor discloses the use of multiple temperature sensors (See Milder column 7, lines 17-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the temperature sensors of Milder to the device of Dobak III, et al. to monitor temperature at various locations along the probe.

11. Claims 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215), further in view of Hammack et al. (U.S. Patent No. 6679906).

In regards to Claims 17, 19 and 20, Milder discloses a system comprising “a probe” (See Figure 14), “first and second concentric channels” (See column 8, lines 32-33), “the first and second concentric channels each having an inlet and an outlet” (See Figure 1), “a source of working fluid” (column 3, lines 22-24), “a pump” (column 6, lines 43-49), “a first temperature sensor” (See Figure 14, element 122, also see column 7, lines 32-38), “a controller” and “the controller receiving feedback” (See column 7, lines 17-40).

Milder does not disclose “a second temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue engaging second temperature sensor”. Attention is directed to the Hammack et al. reference, which in an analogous field of endeavor discloses a temperature sensor mounted radially from the probe (See Hammack et al. column 11, lines 33-61). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Milder with the teaching of Hammack et al. to place a temperature sensor radially from the probe in order to monitor the temperature of a tissue at a distance radially away from the probe.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215) in view of Sieben et al. (U.S. Patent No. 5833688).

In regards to Claim 21, Milder discloses a method of heat transfer and monitoring of tissue comprising “transporting working fluid from a source through an

inner channel of a probe to change a temperature of tissue adjacent the probe” and “transporting the working fluid through a concentric outer channel of the probe back to the source” (See column 4, lines 20-40), and “sensing a first temperature of the tissue at a first location using a first temperature sensor coupled to the probe” (See column 7, lines 32-38).

Milder does not disclose “sensing a second temperature of the tissue at a second location using a second temperature sensor spaced apart from the first temperature sensor, where the difference between the first and second temperatures is used to determine a thermal property of the tissue”. Attention is directed to the Sieben et al. reference, which in an analogous field of endeavor discloses a method of monitoring tissue temperature by comparing temperature readings from multiple temperature sensors (See Sieben et al. column 6, line 47 – column 7, line 13). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the temperature sensor teaching of Sieben et al. to the method of Milder to provide an accurate method of monitoring tissue temperature.

13. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215) in view of Dobak III et al. (U.S. Patent No. 6312452) as applied to claim 12 above, and further in view of Sieben et al. (U.S. Patent No. 5833688).

In regards to Claim 26, Milder in view of Dobak III et al. discloses a method of heat transfer and monitoring of tissue comprising “inserting a probe into tissue, the probe having concentric passageways and a first temperature sensor”, “inserting a

second temperature sensor into the tissue at a predetermined distance from the probe” and directing working fluid through the probe (See Claim 12 Rejection).

Milder in view of Dobak III et al. does not disclose, “comparing the temperature sensed by the first temperature sensor to the temperature sensed by the second temperature sensor for determining a thermal property of the tissue”. Attention is directed to the Sieben et al. reference, which in an analogous field of endeavor discloses a method of monitoring tissue temperature by comparing temperature readings from multiple temperature sensors (See Sieben et al. column 6, line 47 – column 7, line 13). It would have been obvious to one of ordinary skill in the art at the time of the invention to compare sensed temperatures as taught by Sieben et al. to the method of Milder in view of Dobak III et al. provide an accurate method of monitoring tissue temperature.

In regards to Claims 27 and 28, Milder in view of Dobak III et al., further in view of Sieben et al. disclose a method of heat transfer and monitoring of tissue (See Claim 26 Rejection). Milder in view of Dobak III et al. does not disclose “determining the health of the tissue based on comparison” or “determining whether the tissue is alive or dead”. Attention is directed to the Sieben et al. reference a method of monitoring tissue temperature by comparing temperature readings from multiple temperature sensors to determine the health of the tissue (See Sieben et al. column 6, line 47 – column 7, line 13). It is also obvious from the Sieben et al. reference, that ablated tissue have a specific temperature range and once a temperature within that range is met the tissue is dead. It would have been obvious to one of ordinary skill in the art at the time of the

invention to determine the health of the tissue as taught by Sieben et al. to the method of Milder in view of Dobak III et al. provide an accurate method of controlling tissue desiccation.

Allowable Subject Matter

14. Claims 22-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

16. Drawing objections and objections to the specification are withdrawn due to submission of an amendment filed on January 11, 2006.

17. Claim objections for claims 5, 23, 26 and 30 and 35 U.S.C. 112 rejection of claim 18 are withdrawn due to submission of an amendment filed on January 11, 2006.

Claims 1-3, 6-8, 10 and 11

18. Applicant's arguments filed January 11, 2006 have been fully considered but they are not persuasive. In response to applicant's argument that Milder does not disclose "the first and second temperature sensors together adapted to determine a thermal property of a sample", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order

to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 5 and 12-14

19. Applicant's arguments filed January 11, 2006 have been fully considered but they are not persuasive. See response to arguments for claim 1.

Claim 9

20. Applicant's arguments filed January 11, 2006 have been fully considered but they are not persuasive. See response to arguments for claim 1.

Claims 15 and 16

21. Applicant's arguments, see pages 14-15, filed January 11, 2006, with respect to the rejection(s) of claim(s) 15 and 16 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the previously applied art. The new ground(s) of rejection is made in view of Dobak III et al. in view of Milder. In response to applicant's argument that Dobak III et al. does not disclose "a plurality of temperature sensors coupled to the tip for determining a thermal property of the tissue", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 17, 19 and 20

22. Applicant's arguments filed January 11, 2006 have been fully considered but they are not persuasive. See response to arguments for claim 1.

Claims 21-28

23. Applicant's arguments, see pages 16-17, filed January 11, 2006, with respect to the rejection(s) of claim(s) 21 and 26-28 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference(s). The Sieben et al. reference provides the motivation for comparing temperatures and assessing the health of tissue.

24. Applicant's arguments, see pages 16-17, filed January 11, 2006, with respect to claims 22-25 have been fully considered and are persuasive. The 35 U.S.C. 103 rejections of claims 22-25 have been withdrawn.

Claims 29-32

25. Applicant's arguments, see pages 17-18, filed January 11, 2006, with respect to claims 29-32 have been fully considered and are persuasive. The 35 U.S.C. 103 rejections of claims 29-32 have been withdrawn.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

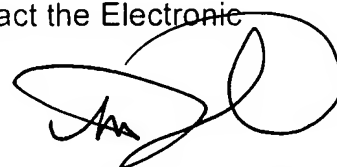
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571) 272-8161. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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